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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,441	08/26/2003	Mark V. Vanderwalle	5490-000313	5180

7590 05/24/2006

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT PAPER NUMBER

3733

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

88

Office Action Summary	Application No.	Applicant(s)	
	10/649,441	VANDERWALLE, MARK V.	
	Examiner	Art Unit	
	Nicholas Woodall	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>✓ 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>✓ 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date <u>08/26/2003</u></p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____ .</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: ____.</p> |
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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed August 26th, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tapered implant engaging section discussed in claim 14 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

Art Unit: 3733

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 20 is objected to because of the following informalities: Claim 20 lines 2 thru 3 state, "selecting the second implant to include a conduit includes selecting at least a bore and an aperture defined by said second implant;". The examiner recommends changing claim 20 lines 2 thru 3 to state, "selecting the second implant to include a conduit, the said conduit including at least a bore and an aperture defined by the said second implant." Appropriate correction is required.
4. Claim 10 states, "The pin implant of claim 9, wherein said second implant engaging section includes a thread which is adapted to operably the second implant." This statement is unclear to what function the thread needs to be adapted to doing. The examiner recommends revising the statement as follows, "The pin implant of claim 9, wherein said second implant engaging section includes a thread which is adapted to operably engage the second implant." Claim 10 will be examined as such.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

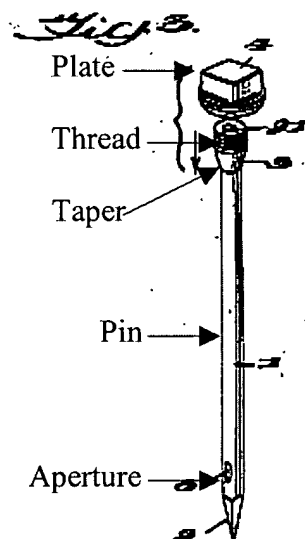
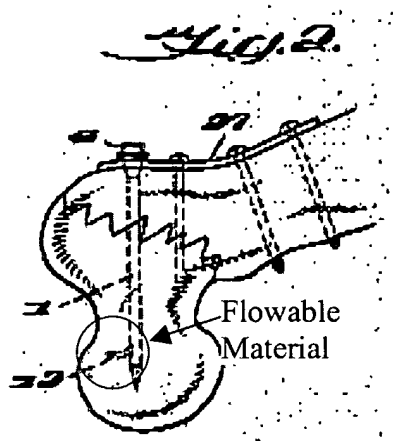
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1- 4 and 6 thru 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Purificato (U.S. 2,631,584).

Regarding claims 1 and 2, Purificato discloses an implant system comprising a plate implant (4) and a pin implant (see figures 1 and 2 below). The characteristics of the pin implant include a distal portion (1) adapted to engage a section of bone. The pin also includes a proximal portion (3) adapted to engage the plate implant. The head of the pin implant is threaded (column 4 lines 48-53) for the purpose of engaging the internal thread of the plate implant (4). The pin implant contains a bore (5) that extends between the proximal portion and distal portion. The pin implant includes an aperture (8) to exterior of the implant. The bore (5) and the aperture (8) create a conduit through the pin implant. Regarding claim 3, Purificato discusses that the plate implant (4) has an internal thread that is complimentary to the threaded head portion of the pin implant (column 4 lines 48-53) and the two implants are connected as shown below in figure 3. Regarding claim 4, the pin implant is smooth and can be inserted into the bone by pounding the pin implant. Regarding claim 6, Purificato teaches that the pasasage (5) through the pin implant is capable of allowing a flowable material (10) to pass through the pin implant and out of the aperture (8) of the pin implant. Regarding claim 7, Purificato discusses that the aperture (8) of the pin implant is drilled at an angle to the longitudinal axis (column 3 lines 27-31). The angled aperture deflects the flowable material (10) out of the aperture and helps the flowable material operably interconnect to the bone. Regarding claim 8, in Purificato the flowable material (10) is added during the primary procedure after the pin implant has been set into the bone. Regarding claim

Art Unit: 3733

9, Purificato discusses a pin implant that is used for fixing a plate implant (4) relative to a selected portion of bone as shown in figure 3 below. The pin implant discussed includes a proximal section that can engage the plate implant (4). The pin also includes a bone engaging section (1) that extends from the plate engaging section of the pin implant. The pin implant also includes a bore (5) that allows a flowable material (10) to pass through the pin implant. The pin implant also includes an aperture (8) on the distal portion of the implant. The distal portion of the pin implant is capable of being passed into the bone. The bore (5) and aperture (8) allow a flowable material (10) to pass through the pin implant and operably engage the bone. Regarding claim 10, Purificato discusses the head (3) of the pin implant to include a thread that engages the internal thread of the plate implant (4). Regarding claim 11, Purificato indicates the pin implant may be made of any biocompatible material (column 2 lines 38-41). Regarding claim 12, Purificato shows a pin implant with a smooth distal portion (1), which allows the pin to easily pass through the bone. Regarding claim 13, the flowable material (10) is inserted through the pin implant during the primary procedure. Regarding claim 14, Purificato shows a tapered section as a lower portion of the head of the pin implant. Regarding claim 15, Purificato shows the aperture (8) located on the distal portion of the pin implant. Regarding claim 16, Purificato shows a bore (5) passing through the pin implant and substantially defines a cannula through the pin implant.

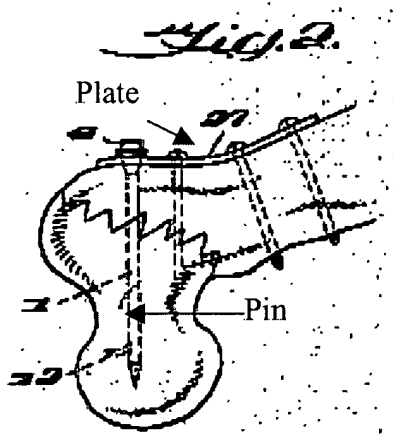


7. Claims 17, 20-21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Purificato (U.S. 2,631,584) as a different interpretation than discussed above.

Regarding claim 17, Purificato teaches a method of fixing a plate implant (27) to a bone portion with a pin implant. Purificato inherently shows positioning the plate implant (27) relative to the selected bone portion, passing the pin implant relative to the plate implant (27), providing a conduit (5) through the pin implant to assist in fixing the pin implant, and flowing a flowable material (10) through the pin implant to interconnect

Art Unit: 3733

the pin implant with the bone as show in figure 2 below. Regarding claim 20, Purificato also shows selecting the pin implant to include a conduit that includes a bore (5) and an aperture (8). This conduit allows flowable material (10) to flow through the pin implant. The flowable material (10) exits the aperture (8) to interconnect the pin implant with the bone portion. Regarding claim 21, Purificato shows interconnecting the pin implant with the plate implant (27) to hold the plate implant (27) relative to the pin implant. Please reference figure 2 below. Regarding claim 23, Purificato shows a pin implant that can be passed into the bone by a pounding or driving force.



Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Purificato (U.S. 2,631,584) in view of Essiger (U.S. 6,302,885). Purificato is discussed above and

fails to teach a pin implant with projections along the distal portion of the pin implant.

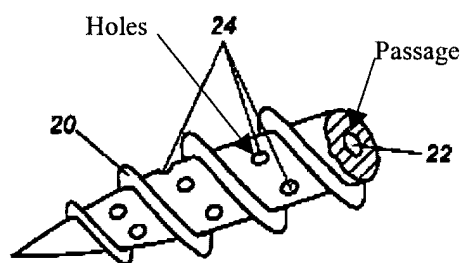
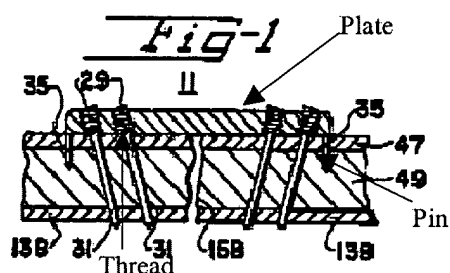
Essiger teaches a number of individual projections (7) distributed about the circumference of the shaft (column 2 lines 31-36). Essiger also teaches the individual projections provide an excellent fixation of the pin implant within the bone (column 2 lines 43-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the implant system of Purificato with the pin having individual projections in view of Essiger to provide an excellent fixation of the pin implant within the bone.

10. Claims 17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markolf (U.S. 3,741,205) in view of Chappius (U.S. 6,565,572). Markolf teaches a method of using a multiple piece implant system that fixes a plate implant relative to a bone portion with a pin implant. Markolf teaches positioning a plate implant (11) relative to a selected portion of bone. Markolf then teaches passing the pin implant (27) relative to a selected portion of the plate implant reference figure 1 below. Markolf also discusses the pin implant (27) having a threaded head (29) portion that is used to interconnect the pin implant (27) with a threaded bore (23, column 4 lines 16-28) of the plate implant (11). The pin implant of Markolf is smooth and can be driven into the bone without deteriorating the effected portion of bone (column 4 lines 28-32). Markolf fails to teach providing a conduit (e.g. bore and aperture) through the pin implant adapted to direct a flow of flowable material through the pin implant to enhance fixing the pin implant to the bone. Chappius teaches providing a passage (22) at least partially through the screw body (12) that join with holes (24) provided along the distal end of the

Art Unit: 3733

bone screw, which are adapted for dispensing medical adhesives, bonding cements, or other flowable materials as shown in figures 2 and 3 below (column 3 lines 49-59).

Chappius also teaches that the flowable materials create a firm fixation to the bone after curing and may strengthen the bone structure (column 4 lines 18-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the pin implant of the system discussed in Markolf with a conduit (e.g. bore and aperture) in view of Chappius to deliver a flowable material, such as bone cement, through the pin implant to the bone to help create a firm fixation between the pin implant and the bone.

**Fig. 2**



11. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please reference PTO-892 for cited art of interest.

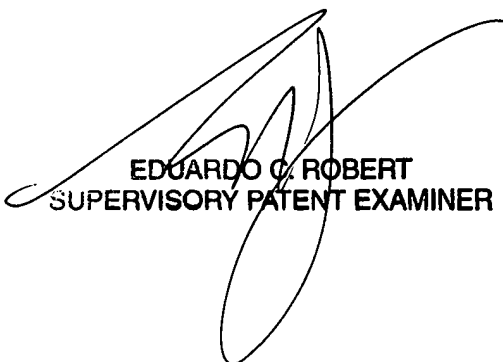
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571) 272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

Art Unit: 3733

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER